CERTIFICATE BY GUIDE

Certified that **DR. RHYTHEM ARORA,** is a bonafide post-graduate student in the department of Oral And Maxillofacial Surgery in M. M. College of Dental Sciences and Research, Mullana, District Ambala, Haryana and is registered with M. M. (Deemed to be) University, Mullana, Ambala. She shall carry out genuine, scientific research work on her dissertation project on **"COMPARATIVE EVALUATION OF IMPLANT STABILITY OF VACUUM PLASMA ACTIVATED AND NON-PLASMA ACTIVATED IMPLANTS BY USING IMPLANT STABILITY QUOTIENT(ISQ)"** under our direct supervision.

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INTRODUCTION

Prosthetic rehabilitation has been an essential part of every medical field including modern dentistry. Since the introduction of titanium dental implants, extensive researches have led to significant improvement of surface topography therefore optimising surface physico- chemistry to promote osseointegration in shorter periods with higher success rates. [1]

Despite having a positive outcome, early and reliable osseointegration remains a critical determinant of clinical success, particularly in cases involving poor bone quality, compromised systemic conditions, or the need for early and immediate loading protocols. It has been established that the implant's primary stability depends on the shape and surface morphology and the secondary stability depends mainly on the implant surface. Critical factors determining the superior bone healing after implant placement includes surface roughness and hydrophilicity. All of these have a direct effect on how an implant integrates into bone as greater the number of cells, faster healing thereby, providing the much needed earlier establishment of stability for functional use.[2]

Further enhancements to improve these characteristics led to the introduction of conventional surface modifications such as sand blasting and acid etching which were established as the gold standard, producing moderately rough surfaces that promote mechanical interlocking with bone and favorable cellular responses.[3] One of the popularly used coatings include calcium phosphate apatite coatings. Implant surfaces are inert and non-calcified when manufactured. To aid in superior biologic characteristics and osseointegration, implant surfaces are subjected to coatings in a thermal environment which densifies implant surfaces with various coatings including hydroxyapatite coatings, bone morphogenesis coatings and many more.

However, due to the property of biological ageing of titanium during storage i.e time dependent degradation of surface leading to a decrease in osteoconductive properties implying adsorption of hydrocarbons from environment on implant surface which decrease the free surface energy leading to increased hydrophobicity, a need arose for technique modifications that would possibly reverse the impaired osteoblastic adhesion

or protein attenuation on surface so that problem of delayed bone healing could be resolved.[4]

Therefore, a variety of chairside methods were introduced including the recent development of activation of implants using plasma and ultraviolet (UV) photo functionalisation. Plasma, the fourth state of matter, is an ionized gas consisting of excited atoms, ions, free radicals and other active substances with dual purposes to explain its applications. Firstly, it has been rendered useful to eliminate carbon surface impurities from implant titanium surfaces and is known to increase the hydrophilicity of the surface without altering its nano or micro topography. This was possible due to plasma of any ionised gas reducing the contact angle to almost 0-10 degrees thereby improving bonding characteristics. Immediately before placement, the implant is subjected to an ionised gas under controlled environmental characteristics which modifies outermost atomic layers. Secondly, its sterilisation properties have proven to be quite useful to eradicate microorganisms including gram-positive bacteria, fungal and yeasts.[5]

After placement a critical factor in determining success of an implant is its stability which by definition states absence of mobility. Although after placement some clinical movements are bound to occur, yet a resistance against these is a direct measurement of the stability and osseointegration. Different loads create different movements on mechanical scale. A variety of methods have been used till date to assess primary as well as secondary stability of implants. More accurately a technique known as Resonance Frequency Analysis (RFA) has gained popularity in recent years to check Implant Stability Quotient (ISQ) values due to its precision and ease of use. Clinical use of RFA is mainly due to its ability to mimic clinical load and directions by applying bending loads to assess implant bone junction interface stiffness. ISQ measures lateral stability. Values in ISQ range anywhere between 0-99 with higher values depicting better and acceptable stability.[6]

To evaluate its efficiency, certain studies have been proposed analysing various parameters. Clinically its effect can be studied by assessing stability quotients of implants at regular intervals.

AIM AND OBJECTIVES

AIM:

This study aims to evaluate and compare implant stability of plasma activated and non-plasma activated implants by using implant stability quotient (ISQ).

OBJECTIVE:

The objective of the study is to evaluate the

- Pain
- Swelling
- Implant stability- primary and secondary
- Osseointegration
- Time of prosthesis loading (days from surgery)
- Failure rate
- The occurrence of any side effects or complications

REVIEW OF LITERATURE

1) **Yoon-Kyung Kim et al (2025)** did a retrospective cohort study including 73 plasma treated implants (using ACTILINK Reborn system) placed in 47 patients with 28 implants in maxilla and 45 implants in mandible over 16 months after carefully considering the exclusion and inclusion criteria to assess implant stability and rate of osseointegration. Only implants able to achieve primary stability of >35 N cm at placement were included in the study. Four different groups of implants were selected with each patient receiving an activated implant after two cycles of 60 seconds each comprising four phases before rendering surface contaminant free without physically altering its properties. After about a month temporary prosthesis was delivered followed by permanent prosthesis two months later with Implant Stability Quotient values measured weekly till week 8. After diligent work for 8 weeks per implant site to assess stability, it was concluded that mandibular and short implants were much more impacted than maxillary and long implants with significant increase in mean stability quotient during earlier days after placement thereby, stating a positive result of study. [3]

2) **Carlo barausse et al(2025)** performed a systemic review to analyse effects on bone implant surface bonding after being exposed to cold atmospheric plasma to alleviate properties of wetting, with research expanding over a period of 20 years culminating in 2025. The primary focus was on learning about bone to implant contact (BIC), implant stability quotient (ISQ), removal torque, bone area fraction occupancy (BAFO), peri implant bone density (PIBD), interfacial bone density(IBD), bone implant direct weight (BDWT) and bone loss measurement, which was assessed on histologic basis on animal models over a population of 71 subjects comprising dogs, pigs and rats with 310 dental implant insertions. A total of 164 implants were subjected to plasma in a closed chamber while the remaining were considered as a

control group with either receiving UV activation or other treatment modalities. Due to a short follow up period of 2-12 weeks, the limitations arose to interpret long term results but evidence suggested a positive outcome with increased efficacy in terms of superior bone parameters following treated implants placement.[4]

3) **Claudio stacchi et al (2025)** did a single blind split mouth randomized control trial for evaluating implant stability during initial phases of placement to assess the effect of plasma activation of dental implants. This study was carried out on 24 patients with each patient receiving one plasma modified and one unmodified implant in each quadrant of the same arch. Immediately before placement, implants were activated using a system - Plasma X motion - MegaGen Implant co. Ltd at pressure less than 10 torr with each cycle lasting for 50 sec in a closed system. Implant stability was checked at 7,14,21,28,42,60 and 90 days using Resonance frequency analysis(RFA) with tabulation of two values i.e mesial and buccal values. As a result, it was found out that plasma activated implants may yield a better outcome as they had higher ISQ(implant stability quotient) values at 60 and 90 days respectively while exhibiting lowest values at 21 days for both groups. [2]

4) **Se Hoon Kahm et al (2024)** studied the effect of vacuum plasma on sand blasted, large grit, acid-etched (SLA) implant surfaces. This study was formulated for 06 rabbit subjects with 18 implant sites to learn about implant stability after plasma treatment of implants on parameters of implant stability quotient (ISQ), histological integration through bone to implant contact (BIC) and bone area ratio (BA). Two groups were made with either of them acquiring either plasma activated using ACTILINK mini or unactivated implants in their femurs where after a time frame of four weeks, subjects were sacrificed to proceed onto next step for study. Implants were subjected to a 60s cycle at 5 torr pressure by maintaining sterility of surface. For experimental groups, implants were placed in proximal femur whereas, for control, distal femur was the area of choice with a safe distance of 1 cm between each implant. ISQ was measured immediately as well as at time of sacrifice with each having six measurements. Histological analysis along with micro CT of bone

volume were done for 60 minutes for each subject. Conclusion was made stating that there was no statistical significant difference between the values obtained after tabulating results of both groups. [8]

5) **Christian Makary et al (2024)** performed a randomized control trial to explore the effect of surface modification using plasma on histologic level. Seven patients were selected as sample size with fourteen mini- implants (3.5 x 8mm) sites, that is, upper arch with sites available on both quadrants were studied. Surface activation was done using a PlasmaX motion machine for a cycle of 50 sec at pressure lower than 10 torr which differentiated XPEED ACTIVE implants(treated) from XPEED implants(untreated) and were placed randomly. After an interval of four weeks, extraction was done of osseointegrated implants for histological examination using trephine drills. Only biopsies with complete bony wall integrity were selected. By virtue of which it was analysed that surface modifications led to increased BIC rate as an active osteoblastic rim was seen depicting high levels of osteoconduction thereby, improving wettability and bone formation characteristics for better outcomes. [9]

6) **Massimo Carossa et al (2022)** did a systemic review to understand effects following treatment using Plasma of Argon (PoA). With Prisma guidelines as basis, and according to PICOS format that is, Population(P), Intervention(I), Comparison(C), Outcome(O), setting(S) articles were segregated. Certain conditions were laid down in form of inclusion of periodontal cell culture and comparison of plasma of argon - treated and non-treated. It was found out that plasma usage accelerated healing in terms of increased titanium surface affinity for osteoblasts in initial phases by increasing surface free energy but no apparent deviation from normal healing patterns were observed in later stages depicting need for further research to prove long term efficacy. [10]

7) **Lei Wang et al (2020)** conducted a study to enhance ageing titanium surfaces using low temperature argon oxygen plasma (LTAOP) or cold plasma. Effects were studied on two substrates – smooth machined titanium (SM Ti) and sandblasted-acid-etched titanium (SLA Ti). Following their activation, Sprague-Dawley rat osteoblasts were inserted to know more about biologic activity of the surface. Contact angle analysis was done to check for surface hydrophilicity. A visible difference was noted as angle reached almost zero after plasma activation. A slight angle increase was noted at consecutive follow ups. Also, relative content of oxygen was found to be increased with diminution of contaminants in the form of carbon. It was concluded that modifying the implant surface led to superior activity of osteoblasts with drastic increase in number and made it more bonding friendly as osteocalcin activity rose thereby, promoting mineralisation of osteoblasts but no morphological conversions were seen. [5]

8) **Paolo Pesce et al (2020)** did a systemic review with meta-analysis to study effects of surface modifications using ultraviolet (UV) and non thermal plasma functionalisation of preclinical studies. Minimum follow up period of 14 days along with sample size of 5 healthy rabbits with at least one dental implant was the basic inclusion criteria. Studies considered were performed on rabbits, rats and beagle dogs. With sample size of four studies on rabbits for meta analysis, it was concluded that both ways of improving bone to implant contact were successful and can be used as per convenience. [11]

MATERIALS AND METHOD

STUDY DESIGN:

This is a randomised comparative interventional study for comparing the efficacy of plasma activated implants with non-treated implants on the basis of Implant stability quotient. The patients will be randomly assigned into 2 groups with the same sample size of 25 people. The First group will consist of patients in which plasma activated implants will be administered, Second group will have patients in which conventional implants will be placed.

STUDY SETTING:

The study will be conducted in the Department of Oral and Maxillofacial Surgery, Maharishi Markandeshwar College of Dental Sciences and Research, Mullana, Ambala. The study will be carried out after due approval from the Institutional Research, Review Board and Institutional Ethical Committee.

SOURCE OF DATA:

Patients reporting for the implant placement procedure to the outpatient department (OPD), Department of Oral and Maxillofacial Surgery, M.M.C.D.S.R, M.M. (Deemed to be University), Mullana, Ambala will be selected for this study. Informed consent will be taken from each patient prior to the surgical procedure

SELECTION CRITERIA:

INCLUSION CRITERIA:

- Patients will be selected irrespective of sex, caste, religion and socio-economic status.

- Patient requiring replacement of any missing tooth.
- Systemically healthy individual
- Co-operative patient
- Ridge of minimum 8mm bone height
- Patient should attain minimum age of 18 years before beginning of procedure with no greater than 70 years to rule out failure rates due to low bone density
- Good oral hygiene
- Patient able to comprehend the whole procedure

EXCLUSION CRITERIA:

- Medically compromised patient.
- Patients with bleeding disorders
- Drug abusers
- Pregnant women
- Uncooperative patients
- The patient does not maintain good oral hygiene.
- Untreated gingival disease

STUDY MATERIAL

- Plasma activator apparatus(BLUEDENT)
- Implants

SAMPLE SIZE

50 patients

SELECTION OF STUDY GROUP:

Patients will be randomly assigned to study group A and B by the supervisor with each group comprising 25 subjects.

PARAMETERS TO BE STUDIED:

- Implant stability(primary and secondary)
- Osseointegration
- Failure rate
- Time of loading (days from placement)
- Swelling
- Pain

ARMAMENTARIUM:

- Plasma activator (BLUEDENT)
- Implants (>8mm in length)
- Implant placement kit
- Resonance frequency analysis(RFA)
- Surgical periodontal probe
- Mouth mirror
- Tweezer
- Surgical handle and blade

- Suction set
- Syringes
- Normal saline
- Periosteal elevators
- Local anaesthetic solutions
- Sutures
- Needle holder

PROCEDURE IN DETAIL:

➔ This study is designed as a randomized clinical trial in which implant stability will be assessed at regular intervals after placement of vacuum plasma treated or non-treated implants till loading of prosthesis.

➔ This study will be performed on people indicated for implant placement due to any reason and will be selected on the basis of the inclusion and exclusion criteria. The patients will be divided into two groups labelled A and B.

➔ A total of 50 subjects will be a part of study with an equal proportion of 25 patients in each group assigned randomly.

➔ Patients will be informed about the study and their consent will be taken prior to this procedure.

➔ Subjects in Study Group A will receive activated implants using plasma and in Study Group B will receive normal sterile implants.

➔ Pre-operative radiographs and Cone Bean Computed Tomography(CBCT) will be assessed.

➔ Nerve blocks will be given along with local infiltration wherever necessary to make the procedure painless and comfortable for the patient.

➔ ISQ values will be assessed at intervals starting from the day of surgical implant insertion till day 90 or until the time the prosthetic crown will be fabricated.

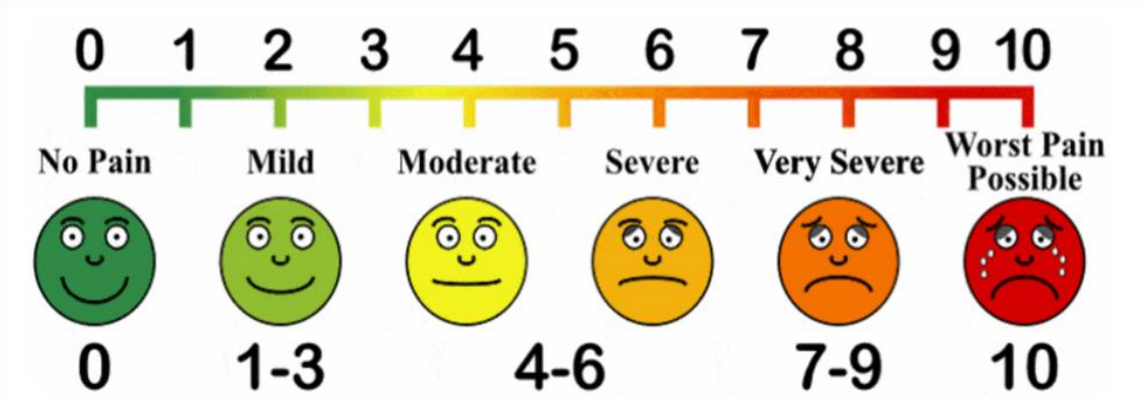
Technique:

- Seat the patient comfortably in the dental chair and drape the patient for sterile field.
- Under all aseptic conditions, after administration of adequate amounts of local anesthetic solutions, a clean incision should be made followed by reflection of mucosal tissue with sufficient periosteal stripping for complete exposure of surgical site.
- This is accompanied with usage of implant drills to create acceptable depth and diameter under copious and continuous normal saline irrigation.
- It is of utmost importance to choose an initial ditch site keeping in mind all biological dimensions necessary for a successful survival rate.
- After accomplishment of requisite parameters, sterile implant will be taken out from packaging and will be subjected to 50 sec cycle in plasma chamber to change its surface characteristics.
- Immediately after activation, the implant will be safely and securely placed into the socket and tightened giving appropriate torque values.
- It is necessary to remove any soft or hard tissue debris from around the site and closure should be made using 3-0 silk in a water tight seal manner.
- Implant Stability quotient values will be assessed using Resonance Frequency Analysis(RFA) which can show measurement from anywhere ranging between 0-100.
- Values will be noted on mesio-distal and bucco-lingual areas.
- Standardized post implant placement instructions will be given to all patients.
- Post placement medications that will be prescribed.
- Patients will be recalled after 7 days for suture removal and assessment of surgical site for inspection of infection or any complication after which healthy healing site will be taken into consideration for next readings of ISQ.
- Regular follow-ups on day 28,45 and 90 days will be made for both control as well as modified surface implant groups to add value to findings.

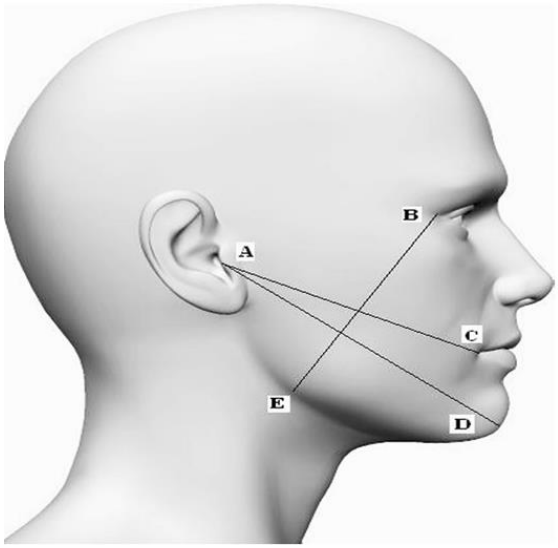
PRE & POST OPERATIVE EVALUATION PARAMETERS

Both the groups will be evaluated on the following clinical parameters:

- **PAIN** -The estimation of pain will be done subjectively
  - ❖ by recording verbal response of the patient
  - ❖ to rate his/her nociceptive experience on **Wong Baker scale** [(10)] which ranges from 0-10.



- **SWELLING** – The assessment of the swelling will be done by using three-line facial swelling measurement **(Nedal,2015)** [(09)]:



★ AC-LINE: The distance in centimetres from the tragus to the outer corner of the mouth.

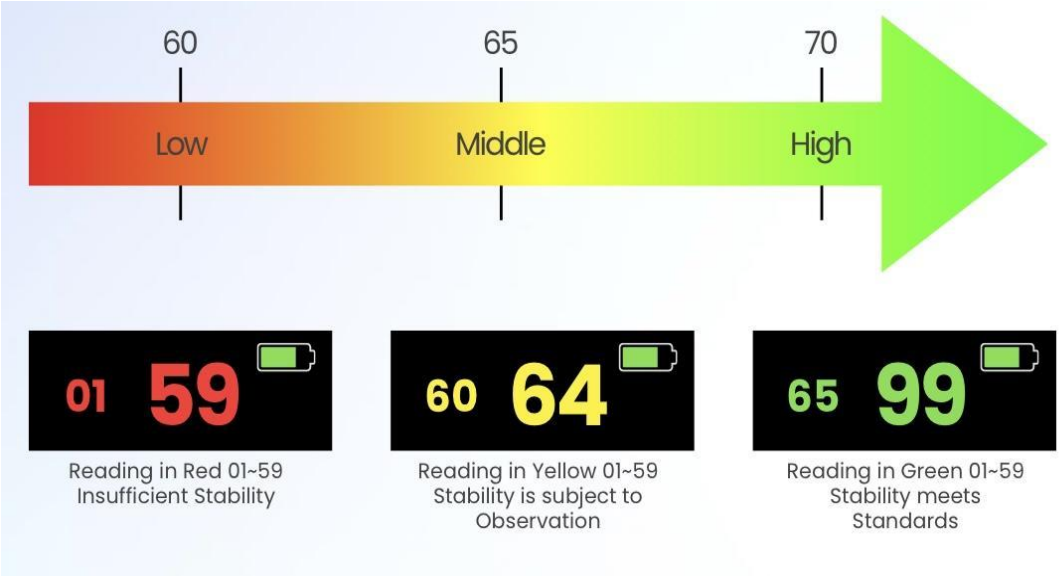
★ AD-LINE: The distance in centimetres from tragus to the prominent point at the midline on the chin.

★ BE-LINE: The distance in centimetres from lateral canthus to the inferior most point on the angle of the mandible

- Implant Stability Quotient(ISQ)- primary as well as secondary stability will be tracked using device I-check implant stability meter without damaging surrounding bone. Readings show a wide range between 0-99 with

  0-59 = low stability
  60-64 = middle range stability
  65-99 = high stability

  ISQ >70 = immediate loading
  ISQ 65-70 = early loading
  ISQ 60-65 = traditional healing



- Osseointegration- to assess bone to implant surface contact
  assessed by clinically checking mobility of implant surfaces with help of two rigid instruments with a force of 500g.

Values will be calculated using the clinical implant mobility scale by Carl E. Mish.[11]

Scale	Description
0	Absence of clinical mobility with 500 g in any direction
1	Slight detectable horizontal movement
2	Moderate visible horizontal mobility up to 0.5 mm
3	Severe horizontal movement greater than 0.5 mm
4	Visible moderate to severe horizontal and any visible vertical movement

- Failure of implant - inability of bone to be formed around the implant surface due to any reason.

  Yes

  No

- Time of prosthesis loading (days after surgery)- to check if activated plasma surface yield earlier and better result to proceed onto step for prosthetic component.

  Loading time-[13]

  Type I (Immediate Implants)- placed directly after tooth extraction

  Type II (Early Implants with soft tissue healing)- placed 4-8 weeks after tooth extraction.

  Type III (Early Implants with partial bone healing)- placed 12-16 weeks after tooth extraction.

  Type IV (Delayed Implants with soft and hard tissue healing)- placed 4 months after tooth extraction.

- Any adverse reaction or outcome during the initial period of 90 days.

- Complications if any such as

  hematoma

  paresthesia

discharge at local site

CLINICAL SIGNIFICANCE

Surface treatment using plasma modifies the external surface of the implant leading to a better adhesion between bone and implant by creating a hydrocarbon free surface thereby, ultimately a better and faster osseointegration due to accelerated protein adsorption along with osteoblastic cells. As a result, earlier secondary stability is achieved which reduces the loading time for prosthesis, creating positive psychological impact by limiting the duration of edentulous period. Dual effects of plasma suggest that not only it makes the implant surface free of impurities but also sterilises the surface of implant therefore alleviating its biological properties of not inducing inflammation and can be safely utilized in every individual. Enhancements in the quantity of growth factors, mesenchymal stem cells, fibroblasts and upregulating of bone regeneration pathways and wound healing accelerates modelling and remodelling of bone. As a result osteoblastic cells favor faster and denser bone formation therefore, success rates soar high.

Conflict of interest: None

Sponsorship: Self

Copyright infringement: None

Risk of subjects: None

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CONSENT FORM

Title of the project "**COMPARATIVE EVALUATION OF IMPLANT STABILITY OF PLASMA ACTIVATED AND NON-PLASMA ACTIVATED IMPLANTS BY USING IMPLANT STABILITY QUOTIENT(ISQ)**"

Participant's name: Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully give consent to participate in the above study.

(I also give consent / do not consent to use my stored biological samples for future scientific purposes: Yes/ No – if applicable)

Signature of the participant: _____ Date:_____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____Date:_____

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★ Lei Wang, Weiwei Wang, Hongmei Zhao, Yanshan Liu, Jie Liu, Na Bai. "Bioactive Effects of Low-Temperature Argon–Oxygen Plasma on a Titanium Implant Surface", ACS Omega, 2020

Publication

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